PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Praveen SHARMA et al.**
Conf. No.: **7331**
Appln. No.: **10/535,414**
Group Art Unit: **1634**
Filed: **November 21, 2003**
Examiner: **Steven C. Pohnert**
For: **Product and Method**

DECLARATION UNDER 37 C.F.R. § 1.132

Assistant Commissioner of Patents
P.O. Box. 1450
Alexandria, Virginia 22313-1450

I, Praveen Sharma, an indian citizen residing at Lille Borgen vei 1A, 0370 Oslo, Norway;

declare as follows:

1. I am an inventor on the present application and the Director of Technology and Product Development at Diagenic AS. I hold a PhD degree in the field of molecular biology.

2. The claims of the instant application concern the use of 351 probes for assessing gene transcript levels and the use of this information for diagnosis, particularly for the diagnosis of breast cancer. The following experiment was conducted to illustrate the utility of these 351 probes for this purpose.

3. Probes comprising the sequences as set forth in the 351 sequences recited in claim 2 (i.e. the Table 2b sequences) were used as probes to analyze breast cancer samples as described in Example 1. A projection plot was generated (Figure 1, Annex) as was generated in Figure 8 (using 345 probes) for breast cancer and normal sample analysis. As with the results presented in Figure 8, the projection plot shows that classification of normal and breast cancer groups is possible. A prediction plot was also generated (Figure 2, Annex) in which the disease samples appear on the x axis at +1 and the non-disease samples appear at -1. The y axis represents the predicted class membership. During prediction, if the prediction is correct, disease samples should fall above zero and non-disease samples should fall below zero. In line with the results shown in Figure 9 of the specification using 345 sequences, the enclosed prediction plot using the 351 sequences of claim 1 illustrates correct prediction of most samples.

3. This data illustrates that very similar results are obtained using the probes as claimed compared to the slightly different sets of probes which were used for the sample analyses in the application as filed. This illustrates that the probes as claimed are suitable for

diagnosis of breast cancer samples according to the methods taught in the application as filed.

4. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Codes, and that such wilful false statements may jeopardize the validity of the application and any patent issuing thereon.

Praveen Sharma 02/09/08

Praveen Sharma Date

ANNEX

Projection and Prediction plots using the claimed oligonucleotide set on breast cancer vs normal samples.

Projection of normal (including benign) and breast cancer samples onto a classification model generated by PLSR using the data of 351sequenced Ids in Table 2b.

PC = Principal Components
N = Normal
C = Breast cancer patients

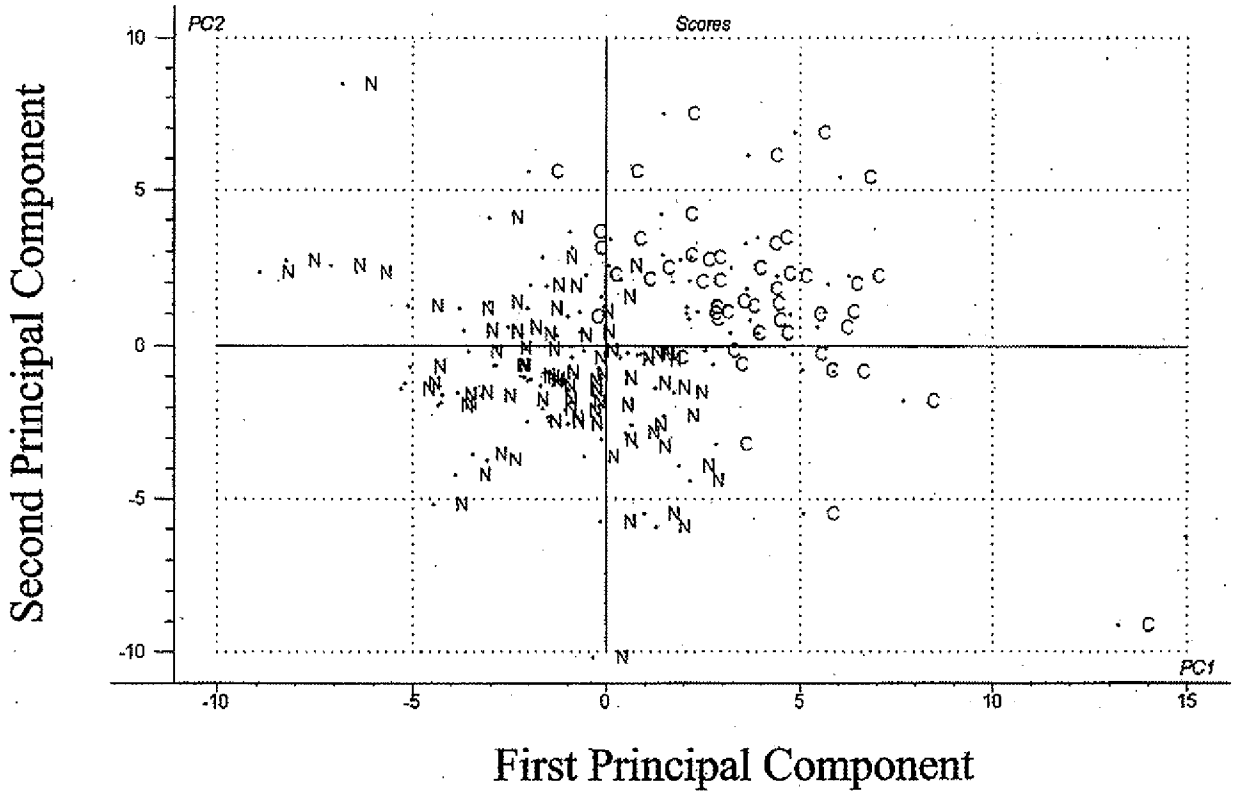

FIGURE 1

Prediction of normal (including benign) and breast cancer samples based on 2 principal components using the data of 351sequenced Ids in Table 2b.

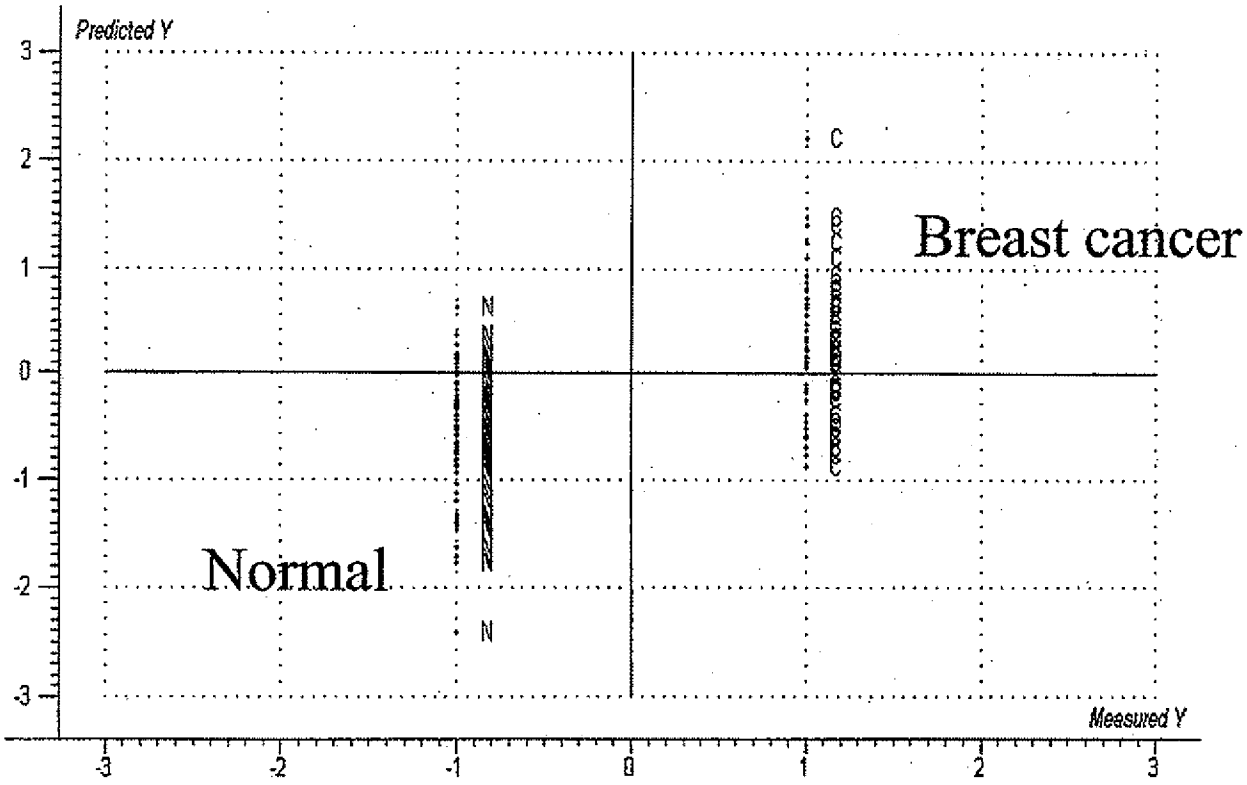

FIGURE 2